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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,717	05/02/2001	Soren Nielsen	NIELSEN=3B	3818

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BROWDY AND NEIMARK, P.L.L.C.
624 Ninth Street, N.W.
Washington, DC 20001

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,717

Applicant(s)

NIELSEN ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 12-18, 20, 23-30, 35-42 and 44-50 is/are pending in the application.
4a) Of the above claim(s) 3, 4, 6, 7, 12-18 and 24 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 2, 5, 23, 26-30, 36-42, 46 and 50 is/are rejected.
7) ☒ Claim(s) 20, 25, 35, 44, 45 and 47-49 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

RD

Status of Application, Amendments and/or Claims

The amendment filed 14 June 2005 has been entered in full. Claims 31-34 and 43 are cancelled. New claims 44-50 are added. Claims 1, 2, 5, 20, 23, 25-30, 35-42, 44-50 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The Declaration of Else Tonnesen filed 14 June 2005 is sufficient to overcome the rejection to claims 1 and 20 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, as set forth at pages 3-4 of the previous Office Action (14 December 2004).

The rejection to claims 1, 30-32, 34, 37, 38, 42 and 43 under 35 U.S.C. 112, first paragraph, scope of enablement, as set forth at pages 4-7 of the previous Office Action (14 December 2004), is *withdrawn* in view of the amendment (14 June 2005).

The rejection to claims 1 and 5 under 35 U.S.C. 112, first paragraph, written description, new matter, as set forth at pages 7-8 of the previous Office Action (14 December 2004), is *withdrawn* in view of the amendment (14 June 2005).

The rejection to claims 37-43 under 35 U.S.C. 112, second paragraph, as set forth at pages 8-9 of the previous Office Action (14 December 2004), is *withdrawn* in view of the amendment (14 June 2005).

The objection to the specification because of failure to comply with 37 CFR 1.821-1.825 of the Sequence Rules and Regulations, as set forth at pages 12-13 of the previous Office Action (14 December 2004), is *withdrawn* in view of Applicant's arguments (14 June 2005).

Claim Rejections - 35 USC § 102(b)

Claims 1, 2, 5, 23 and 39 remain rejected under 35 U.S.C. 102(b) as being anticipated by Akamatsu *et al.*, US Patent No. 4,745,099 (cited in previous Office Action). The basis for this rejection is set forth at page 9 of the previous Office Action (14 December 2004).

Applicant argues that anemia is a symptom of the malignant tumor and that you do not treat the underlying disease by treating the symptoms of the disease. Applicant argues whether the malignancy-induced anemia would be responsive to EPO. Applicant argues that the objective for the EPO treatment in Akamatsu *et al.* is alleviation of anemia and anemia cannot be viewed as a condition characterized by acute inflammation of the lung and airways.

Applicant's arguments have been fully considered but are not deemed persuasive. The instant claims do not state **"a method for the treatment or prophylaxis of acute inflammation of the lung or airway"** (Emphasis added). The instant claims are broadly drawn to "a method for the treatment or prophylaxis of a non-ischemic condition, **characterized by acute inflammation of the lung or airway**" (Emphasis added).

Akamatsu *et al.* teach the administration (single dose or continued administration; column 3, lines 44-52; column 6, lines 30-68 and claims) of human EPO for treatment of the anemia of malignant tumors (non-ischemic condition) (abstract, claims). Akamatsu *et al.* teach the administration of EPO in Lewis lung carcinoma mouse models (column 6, lines 29-52 and Figures 1 and 2). Akamatsu *et al.* teach the alleviation of anemia in the carcinoma mouse models upon administration of erythropoietin (column 6, lines 29-52 and Figures 1 and 2). Lewis lung carcinoma mouse models would exhibit inflammation of the lung or airways. EPO is used in the cancer treatment.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections - 35 USC § 103(a)

Claims 1, 26-30, 36, 40-42, 46, 50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Akamatsu *et al.*, US Patent No. 4,745,099 in view of Delgado Hernandez *et al.*, Neuroimmunomodulation 6:187-192, 1999 (cited in the previous Office Action). The basis for this rejection is set forth at page 9 of the previous Office Action (14 December 2004).

Applicant incorporates their response to the rejection under 35 U.S.C. 102(b) as being anticipated by Akamatsu *et al.*, US Patent No. 4,745,099 in the instant rejection under 35 U.S.C. 103(a) as being unpatentable over Akamatsu *et al.*, US Patent No. 4,745,099 in view of Delgado Hernandez *et al.*, Neuroimmunomodulation 6:187-192,

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1999. Applicant states that Delgado Hernandez *et al.* shows that alpha-MSH may have an effect on myeloperoxidase in LPS-induced lung inflammation, which suggest that alpha-MSH treatment may have an effect that could be associated with inhibition of neutrophils. Applicant argues that the Delgado Hernandez *et al.* reference provides no data supporting that EPO could have anti-inflammatory effects in lung disease.

Applicant's arguments have been fully considered but are not found to persuasive for the reasons discussed above in the maintained 35 U.S.C. 102(b) rejection as being anticipated by Akamatsu *et al.*, US Patent No. 4,745,099.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Objections

Applicant has submitted the Declaration of Else Tonnesen (14 June 2004). The instant declaration, while considered, is objected to because it is not clear whether the declaration has been submitted under 37 CFR 1.131 or 37 CFR 1.132.

Claims 20, 25, 35, 38, 44, 45, 47-49 remain objected. The basis for this rejection is set forth at page 12 of the previous Office Action (14 December 2004).

Claims 20, 25, 35, 44, 45, 47-49 remain objected to because they depend from a rejected claim.

Claim 38 remain objected to because it's drawn to an improper Markush group (see line 14).

New Rejections:

Claim Rejections - 35 USC § 112, First Paragraph, Written Description, New Matter

Claims 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed: "wherein the peptide further comprises the sequence A1-B2-C3-D4" (claim 37) and "wherein the peptide further comprises the sequence R1-W-X-Y-Z-R2" (claim 38).

Applicant's amendment, filed 14 June 2004, asserts that no new matter has been added. Applicant states that claims 37 and 38 has been amended to be dependent on claim 28. Applicant, however, fails to provide sufficient direction for the written description for the above-mentioned "limitations".

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The instant claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed. Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide **specific sufficient written support** for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Objections

Claims 28 and 36 are objected to because the instant claims appear to read on the same scope. The instant claims comprise very similar steps, which raises the question of similar scope. If the claims are not of similar scope, Applicant is asked to specifically point in the specification, the patentable distinction between the claims.

Conclusion

No claims are allowed.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

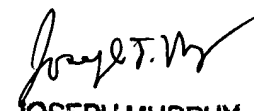
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RMD
8/22/05


JOSEPH MURPHY
PATENT EXAMINER